

**TESTIMONY OF CAROL M. BROWNER  
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BEFORE THE  
SUBCOMMITTEES ON HEALTH AND ENVIRONMENT  
AND OVERSIGHT AND INVESTIGATIONS  
OF THE  
COMMITTEE ON COMMERCE  
U.S. HOUSE OF REPRESENTATIVES**

**May 15, 1997**

Messrs. Chairmen, Members of the Subcommittees, thank you for inviting me to discuss the Environmental Protection Agency's (EPA's) proposed revisions to the national ambient air quality standards for particulate matter and ozone.

On these two pollutants, over the past three-and-a-half years, EPA has conducted one of its most thorough and extensive scientific reviews ever. That review is the basis for the new, more stringent standards for particulate matter and ozone that we have proposed in order to fulfill the mandate of the Clean Air Act.

On average, an adult breathes in about 13,000 liters of air each day. Children breathe in 50 percent more air per pound of body weight than do adults.

For 26 years, the Clean Air Act has promised American adults and American children that they will be protected from the harmful effects of dirty air -- based on best available science. Thus far, when you consider how the country has grown since the Act was first passed, it has been a tremendous success. Since 1970, while the U.S. population is up 28 percent, vehicle miles travelled are up 116 percent and the gross domestic product has expanded by 99 percent, emissions of the six major pollutants or their precursors have dropped by 29 percent.

The Clinton Administration views protecting public health and the environment as one of its highest priorities. We have prided ourselves on protecting the most vulnerable among us -- especially our children -- from the harmful effects of pollution. When it comes to the Clean Air Act, I take very seriously the responsibility the Congress gave me to set air quality standards that "protect public health with an adequate margin of safety" -- based on our reading of the best science available.

The standard-setting process includes extensive scientific peer review from experts outside of EPA and the federal government. Based on our reading of the best available science, I have proposed new standards for particulate matter and ozone that I believe are required to protect the health of the American people.

Under the law, we are not to take costs into consideration during the standard setting phase of the process. This has been the case through six Presidential administrations and 14 Congresses, and has been reviewed by the courts. We believe this approach remains appropriate. However, once we revise any given air quality standard, it is both appropriate and, indeed, critical that we work with states, local governments, industry and others to develop the most cost-effective, common-sense strategies and programs possible to meet those new health standards.

I want to be clear that at this point we have only proposed revisions to the standards for these two pollutants and we are reviewing comments on them. We take very seriously our obligation to carefully consider all public comments on these proposals before making a final decision. We have heard from small businesses, industry, state and local governments, federal agencies, and other citizens like the elderly, children, doctors and people with asthma. While we have proposed specific

levels for each pollutant, we also asked for comment on a wide range of alternative options. I do not intend to make a final decision until comments on all of those alternative options have been carefully considered.

I would like to describe for you the basis for my recent decisions to propose revisions to the particulate matter and ozone standards. I would also like to discuss some of the innovative approaches we are undertaking to ensure that any newly revised standard would be met in the most common-sense, cost-effective way possible.

### **Background**

The Clean Air Act directs EPA to identify and set national standards for certain air pollutants that cause adverse effects to public health and the environment. EPA has set national air quality standards for six common air pollutants -- ground-level ozone (smog), particulate matter (measured as PM-10, or particles 10 micrometers or smaller in size), carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide.

For each of these pollutants, EPA sets what are known as "primary standards" to protect public health. EPA can also establish "secondary standards" to protect the public welfare, including the environment, crops, vegetation, wildlife, buildings and monuments, visibility, climate, soils, water, economic value, and so forth.

Under the Clean Air Act, Congress directs EPA to review these standards for each of the six pollutants every five years. The purpose of these reviews is to determine whether the scientific research available since the last review of a standard indicates a need to revise that standard. The ultimate purpose is to ensure that we are continuing to provide adequate protection of public health and the environment. Since EPA originally set the national air quality standards (most were set in 1971), only two of

EPA's reviews of these standards have resulted in revised primary standards -- in 1979, EPA revised the ozone standard to be less stringent; and in 1987, EPA revised the particulate matter standard to focus on smaller particles (those less than 10 micrometers in diameter), instead of all sizes of suspended particles.

By the early 1990's, about 3,000 new studies had been published on the effects of ozone and there was an emerging body of epidemiological studies showing significant health effects associated with particulate matter. EPA was sued by the American Lung Association to complete its ongoing ozone review and make decisions on both the ozone and particulate matter standards. In March 1993, I announced my decision not to revise the ozone standards at that time and committed to accelerate the next review in light of new scientific evidence on human health effects. A number of public peer review meetings were held on the new studies and on the draft Criteria Document throughout 1993. Soon afterwards, in February 1994, I issued a Federal Register notice committing the Agency to meeting an expedited schedule for completion of the scientific assessment and review of the standards. The scientific analysis and review for both pollutants are completed and EPA proposed revisions to the two standards late last year. I have previously stated my intention to announce final decisions on both pollutants by July 19, 1997.

Although the reviews for both the ozone and particulate matter standards have been accelerated, I gave them very high priority and focused the necessary resources on them to ensure that we conducted an exhaustive and open review of the science. The criteria documents alone were six inches thick for particulate matter and three inches thick for ozone. I believe that our decision-making process on ozone and

particulate matter has been thorough, complete and, as I will describe, based on extensive peer-reviewed science.

**Extensive Scientific Review Process  
Used to Review the Ozone and Particulate  
Matter National Air Quality Standards**

EPA undertakes an extensive scientific and technical assessment process during the standard review for each air pollutant. This includes developing (1) a "criteria document" which reflects the latest scientific knowledge on the kind and extent of all identifiable effects on public health or welfare of the pollutant, and (2) a detailed scientific and technical assessment, known as a "staff paper." Using information in the criteria document, the staff paper arrays a range of policy alternatives based on the scientific evidence and makes recommendations to me. Both of these documents go through extensive public and external scientific peer review.

The "criteria document" is a comprehensive assessment that includes hundreds or sometimes thousands of studies that have been published in peer review journals. My Office of Research and Development holds a series of peer review workshops on draft chapters of the criteria document. Once the entire document has been completed in draft form, it is further reviewed by the public and the Clean Air Scientific Advisory Committee, or CASAC.

As you know, the CASAC is a Congressionally established panel of external science experts appointed by EPA. During the review for each air pollutant, the panel is augmented with additional scientific and technical consultants who have expertise related to that pollutant and its effects. In total, there were 21 scientists and technical

experts from academia, research institutes, public health organizations and industry who reviewed the particulate matter criteria document and staff paper, and 16 who reviewed the ozone criteria document and staff paper. The recent ozone and particulate matter CASAC reviews were chaired by George Wolff, an atmospheric scientist from General Motors. CASAC meetings are open to the public.

The CASAC panel reviews the draft criteria documents and the key underlying studies, and makes recommendations for revisions to the criteria document. Industry, state and local agencies, and other members of the public also submit extensive comments on the draft criteria documents. My staff then revises the document and submits it for another review by the CASAC and the public. This process sometimes repeats itself two or three times until the CASAC sends EPA what is known as a "closure" letter, pronouncing the criteria document as adequate to be used as a basis for a decision on whether or not a given standard should be revised.

Staff in my Office of Air and Radiation also develops a "staff paper." The purpose of the staff paper is to identify the most policy-relevant information contained in the criteria document and the critical elements that the EPA staff believes should be considered in the review of the standards. The staff paper typically includes quantitative exposure and risk analyses. This document also includes staff recommendations of ranges of alternative standards that should be considered in any decision I may make on revising a standard. Like the criteria document, this draft staff paper is subject to review by the public and the CASAC panel. And like the criteria document, the staff paper often undergoes two or more reviews -- where the scientific panel recommends changes and my staff responds to those recommendations --

before the CASAC issues a letter of "closure" on it as well. At that point the staff paper, along with the criteria document, is ready for me to use in deciding whether it is appropriate to propose any revisions to the standards.

### **Public Involvement in the Ozone and Particulate Matter Decisions**

Throughout the three-and-a-half year process of developing our proposed standards, we have remained committed to analyzing the science in an open public forum and ensuring broad public input. In February 1994, for example, we published in the Federal Register the schedule we intended to follow for the review of the ozone standard which identified the opportunities for public comment and public meetings.

Each meeting held with the CASAC on criteria documents and staff papers is open to the public. For the ozone and particulate matter reviews, we held 11 CASAC meetings totaling more than 124 hours of public discussion on the criteria documents and staff papers. All of these meetings were announced in the Federal Register and open to the general public. In addition to the public meetings and the public review and comment on the criteria documents and staff papers, the public has had several other opportunities to provide input to a decision on the ozone and particulate matter standard revisions.

In June 1996, EPA published in the Federal Register an Advance Notice of Proposed Rulemaking describing the key issues under consideration and time frames for decisions on the two standards. In July 1996, we held national public meetings in Philadelphia and St. Louis, where we presented these key issues and options we were considering on the two standards and received extensive comments from the public.

About 100 representatives of industry, state and local governments, and members of the public provided comments at those meetings.

When I announced the proposed revisions last November, I established a virtually unprecedented system for the public to provide their comments. In addition to the normal docketing process for receipt of public comments, I had a national toll-free telephone hotline (1-888-TELL-EPA) established to encourage the broadest amount of public comment possible. During the public comment period EPA received more than 14,000 calls from the public.

We have also made several key documents, including the staff papers, criteria documents, and risk assessments, available to the public over the Internet. We established a system for people to submit their comments via E-mail over the Internet. We received more than 4,000 comments through E-mail during the public comment period. Again, my goal was to encourage the broadest array of public comment possible.

We also held two days of public hearings on the proposed standard revisions in each of three cities -- Salt Lake City, Chicago and Boston. In addition, we held a day-long public hearing in Durham, North Carolina on our associated proposal for air quality monitoring for particulate matter. At these hearings, more than 400 citizens and organizations provided testimony about their views of our proposed standards.

Overall, we have received over 40,000 written comments on the proposed standards from the public, trade associations, industry, environmental organizations, states and others. The involvement by outside groups on the proposed standards far exceeds that taken on any other previous standard review.



We have taken other steps to expand the public discourse on these matters. We have held two national satellite telecasts broadcast around the Nation to answer questions on the standards from officials from state and local governments, industries and other groups. We also worked with the Air and Waste Management Association, a national organization of industry, government and other air pollution control experts, to hold public meetings on the new standards at more than ten different locations. Beyond that, my regional offices have held public forums around the Nation to discuss the issues associated with any possible revision to these air quality standards. My regional office staff also participated in hearings that states such as California, Texas and Washington and cities like New York City held on these proposed standard revisions.

#### **Interagency Review Process for the Proposed Revisions to the Ozone and Particulate Matter Standards**

In 1993, EPA and the Office of Management and Budget (OMB) set up an Interagency Work Group to closely follow the review of the national air quality standards for ozone and particulate matter. Beginning in 1994 and throughout the remainder of the review process, EPA and OMB held fourteen meetings with representatives of other offices and Agencies to discuss the health science studies and EPA's scientific review documents and analyses. This proposal process culminated in the review of the proposed standards under E. O. 12866 by OMB with the Interagency Work Group. Several technical and policy meetings were held among EPA, OMB and representatives from the various other Departments and Agencies in November 1996 to discuss their

comments and concerns. Following these discussions, we made changes to the Federal Register preamble in a number of areas to ensure that there was full presentation of all the issues on which EPA was seeking public comment.

Beginning in February 1997, EPA has been actively participating in weekly meetings of both an Interagency Technical Work Group and an Interagency Policy Work Group convened by EPA and the Office of Management and Budget. These meetings are designed to discuss the rationale for the proposals, new information and analysis prepared by EPA, EPA's response to public comments, and the rationale for the final decision. This process has involved the Departments of Interior, Treasury, Commerce, Agriculture, Defense, Transportation, and Justice, the Small Business Administration, Office of Science Technology and Policy, and the Council of Economic Advisors. These Departments and Agencies have already invested more time in this review process than for any previous revision of a national air quality standard. They are investing significant time in reading EPA's supporting documents and extensive public comments on the proposed standards in order to help them provide meaningful comments for my final decision.

#### **Rationale for EPA's Proposed Revision of the Ozone Standards**

Since the mid-1980's, there have been more than 3,000 scientific studies published that are relevant to our understanding of the health and environmental effects associated with ground-level ozone. These peer-reviewed studies were published in independent scientific journals and included controlled human exposure studies, epidemiological field studies involving millions of people (including studies tracking

children in summer camps), and animal toxicological studies. Taken as a whole, the evidence indicates that, at levels below the current standard, ozone affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. Indeed, one of the groups most exposed to ozone is children who play outdoors during the summer ozone season.

Certain key studies, for example, showed that some moderately exercising individuals exposed for 6 to 8 hours at levels as low as 0.08 parts per million (ppm) (the current ozone standard is set at 0.12 ppm and focuses on 1-hour exposures) experienced acute adverse health effects such as decreased lung function, respiratory symptoms, and lung inflammation. Other recent studies also provide evidence of an association between elevated ozone levels and increases in hospital admissions. Animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to ozone over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

As a result of these and other studies, EPA's staff paper recommended that the current ozone standard be revised from the current one-hour form (that focuses on the highest "peak" hour in a given day) to an 8-hour standard (that focuses on the highest eight hours in a given day). It also recommended setting an 8-hour standard in the range of 0.07 ppm to 0.09 ppm, with multiple exceedances (between one and five per year).

The CASAC panel reviewed the scientific evidence and the EPA staff paper and was unanimous in its support of eliminating the one-hour standard and replacing it with an eight-hour standard. While I do not base my decisions on the views of any individual

CASAC member (as a group they bring a range of expertise to the process), it is instructive to note the views of the individual members on these matters. While ten of the 16 CASAC members who reviewed the ozone staff paper expressed their preferences as to the level of the standard, all believe it is ultimately a policy decision for EPA to make. All ten favored a multiple exceedance form. Of the four human health experts on the CASAC panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm. No panel member favored a standard level of 0.07 ppm; three others favored 0.09 ppm, and one favored either 0.09 or 0.10 ppm combined with new public health advisories when ozone concentrations are at or above 0.07 ppm.

Consistent with the range of standards viewed as appropriate by CASAC scientists and included in the EPA staff paper, we proposed a new eight-hour standard at 0.08 ppm, with a form that allows for multiple exceedances, by taking the third highest reading each year and averaging those readings over three years. We asked for comments on a number of alternative options, ranging from eight-hour levels of 0.07 to 0.09 ppm to an option that would retain the existing standard. Just as a point of reference, based on our recent analysis of children outdoors in 9 cities throughout the country, the current one-hour ozone standard of 0.12 ppm is roughly equivalent to a 0.09 ppm 8-hour standard with approximately two to three exceedances.

We considered a number of complex public health factors in reaching the decision on the level and form proposed. The quantitative risk assessments that we performed indicated differences in risk to the public among the various levels within the recommended ranges, but they did not by themselves provide a clear break point for a

decision.<sup>1</sup> EPA's risk assessments showed that hundreds of thousands of children would obtain additional protection under a revised standard.

Also, consistent with EPA's prior decisions over the years, I determined that setting an appropriate air quality standard for a pollutant for which there is no discernible threshold means that factors such as the nature and severity of the health effects involved, and the nature and size of the sensitive populations exposed, are very important. As a result, I paid particular attention to the health-based concerns reflected in the independent scientific advice and gave significant consideration to the advice of the health professionals on the CASAC. This is particularly important given the fact that one of the key most exposed populations would be children active outdoors. The decision to propose at the 0.08 ppm level reflects this, because, though it is in the middle of the range recommended for consideration by CASAC and the EPA staff paper, as a policy choice it reflects the lowest level recommended by individual CASAC panel members and it is the lowest level tested and shown to cause effects in controlled human-exposure health studies. Of the four human health experts on the CASAC panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm.

Finally, air quality comparisons have indicated that meeting a 0.08 ppm, third highest concentration, eight-hour standard (as proposed by EPA) would also likely result in nearly all areas not experiencing days with peak 8-hour concentrations above

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<sup>1</sup>CASAC itself agreed that there are a continuum of effects -- even down to background -- and that there is no "bright line" distinguishing any of the proposed standards as being significantly more protective of public health.

the upper end of the range (0.09 ppm) referred to in the CASAC closure letter and the EPA staff paper. Given the uncertainties associated with this kind of complex health decision, EPA has also looked at the reduction in people exposed to ozone concentrations that are above the highest level recommended by any member of the CASAC panel (i.e., 0.09 ppm). Recent air quality data indicate that meeting a 0.08 ppm third-highest concentration (as proposed by EPA) would result in all but 1% of areas avoiding days with peak 8-hour concentrations above the 0.09 ppm level. By comparison, a 0.08 ppm standard set at the upper end of the range of concentrations (5th highest) would result in 17% of areas exceeding the 0.09 level.

It is also important to note that ozone causes damage to vegetation including:

- interfering with the ability of plants to produce and store food, so that growth, reproduction and overall plant growth are compromised;
- weakening sensitive vegetation, making plants more susceptible to disease, pests, and environmental stresses; and,
- reducing yields of economically important crops like soybeans, kidney beans, wheat and cotton.

Nitrogen oxides are a class of the key pollutants that causes ozone. Controlling these pollutants also reduces the formation of nitrates that contributes to fish kills and algae blooms in sensitive waterways, such as the Chesapeake Bay.

As part of its review of the ozone science, the CASAC panel unanimously advised that EPA set a secondary standard more stringent than the current standard in order to protect vegetation from the effects of ozone. However, agreement on the level and form of the secondary standard was not reached.

## **Rationale for EPA's Proposed Revision to the Particulate Matter Standards**

For the particulate matter standard review, EPA assessed hundreds of peer reviewed scientific research studies, including numerous community-based epidemiological studies. Many of these community-based health studies show associations between particulate matter (known as PM) and serious health effects. These include premature death of thousands of elderly people or others with heart and/or respiratory problems each year. Other health effects associated with exposure to particles include aggravation of respiratory and cardiovascular disease, including more frequent attacks of asthma in children. The results of these health effects have been significantly increased numbers of missed work and school days, as well as increased hospital visits, illnesses, and other respiratory problems.

The recent health studies and a large body of atmospheric chemistry and exposure data have focused attention on the need to address the two major subfractions of PM-10 -- "fine" and "coarse" fraction particles -- with separate programs to protect public health. The health studies have indicated a need to continue to stay focused on the relatively larger particles or "coarse" fraction that are a significant component of PM-10 and are controlled under the current standards. We continue to see adverse health effects from exposures to such coarse particles above the levels of the current standards. As a result, CASAC scientists agreed that existing PM-10 standards should be maintained for the purpose of continuing to control the effects of exposure to coarse particles.

However, twenty-one of the new health and atmospheric science studies have highlighted significant health concerns with regard to the smaller "fine" particles (those at or below 2.5 micrometers in diameter) or "fine" particle indicators. These particles are so small that several thousand of them could fit on the type-written period at the end of a sentence. In the simplest of terms, fine particles are of health concern because they can remain in the air for long periods, both indoors and outdoors, and can easily penetrate and be absorbed in the deepest recesses of the lungs. These fine particles can be formed in the air from sulfur or nitrogen gases that result from fuel combustion and can be transported many hundreds of miles. They can also be emitted directly into the air from sources such as diesel buses and some industrial processes. These fine particles are not only associated with serious health effects, but they also are a major reason for visibility impairment in the United States in places such as national parks that are valued for their scenic views and recreational opportunities. For example, visibility in the eastern United States should naturally be about 90 miles, but has been reduced to under 25 miles.

EPA analyzed peer-reviewed studies comparing death rates and particle concentrations in cities with populations of more than five-and-a-half million people that directly related effects of "fine" particle concentrations to human health. Another study of premature mortality tracked almost 300,000 people over the age of 30 in 50 U.S. cities. After adjusting for the other risk factors for that population, PM-2.5 concentrations were found to be associated with a 17 % increase in total mortality between cities with the least and most polluted air.



Based on the health evidence reviewed, the EPA staff paper recommended that EPA consider adding "fine particle" or PM-2.5 standards, measured both annually and over 24 hours. The staff paper also recommended maintaining the current annual and/or 24-hour PM-10 standards to protect against coarse fraction exposures, but in a more stable form for the 24-hour standard. This more stable form would be less sensitive to extreme weather conditions.

When CASAC reviewed the staff paper, 19 out of 21 panel members recommended establishment of new standards (daily and/or annual) for PM-2.5. They also agreed with the retention of the current annual PM-10 standards. Fourteen of twenty-one CASAC members favored consideration of retention of the 24-hour PM-10 standard in a more stable form.

Regarding the appropriate levels for PM-2.5, staff recommended consideration of a range for the 24-hour standard of between 20 and 65 micrograms per cubic meter (ug/m<sup>3</sup>) and an annual standard to range from 12.5 to 20 ug/m<sup>3</sup>. Individual members of CASAC expressed a range of opinions about the levels and averaging times for the standards based on a variety of reasons. Four panel members supported specific ranges or levels within or toward the lower end of the ranges recommended in the EPA staff paper. Seven panel members recommended ranges or levels near, at or above the upper end of the ranges specified in the EPA staff paper. Eight other panel members declined to select a specific range or level.

Consistent with the advice of the EPA staff paper and CASAC scientists, in November last year, I proposed adding new standards for PM-2.5. Specifically, based on public health considerations, I proposed an annual standard of 15 ug/m<sup>3</sup> and a 24-

hour standard of 50 ug/m<sup>3</sup>. In terms of the relative protection afforded, this proposal is approximately in the lower portion of the ranges or options recommended by those CASAC panel members who chose to express their opinions on specific levels. However, taking into account the form of the standard proposed by EPA, we understand that the proposal would fall into the lower to middle portion of the ranges or options. In order to ensure the broadest possible consideration of alternatives, I also asked for comment on options both more and less protective than the levels I proposed.

Also consistent with the advice of the EPA staff paper and fourteen of twenty-one CASAC scientists, I proposed to retain the current annual PM-10 standard and to retain the current 24-hour PM-10 standard, but with a more stable form. I also requested comment on whether the addition of fine particle standards and the maintenance of an annual PM-10 standard means that we should revoke the current 24-hour PM-10 standard.

As has been the case throughout the 25-year history of environmental standard setting, uncertainty has played an important role in decision making on the particulate matter standards. Specifically, the uncertainty about the exact mechanism causing the observed health effects has led some to argue that not enough is known to set new or revised standards. In this case, however, because of the strong consistency and coherence across the large number of epidemiological studies conducted in many different locations, the seriousness and magnitude of the health risks, and/or the fundamental differences between "fine" and "coarse" fraction particles, the CASAC scientists and the experts in my Agency clearly believed that "no action" was an inappropriate response. The question then became one of how best to deal with

uncertainty -- that is, how best to balance the uncertainties with the need to protect public health.

Given the nature and severity of the adverse health effects, I chose to meet the Congressional requirement of providing the public with an "adequate margin of safety," by proposing PM-2.5 standards within the ranges recommended in the EPA staff paper and commented upon in the CASAC closure letter. I believe the levels chosen are consistent with the independent, scientific advice given me about the relationship between the observed adverse health effects and high levels of fine particle pollution. That advice led to a proposed decision toward the lower end of the range of levels for the annual standard, which is designed to address widespread exposures, and toward the middle of the range for the 24-hour standard, which would serve as a backstop for seasonal or localized effects.

One final note on particulate matter. Some have suggested we need more research before decisions are made about these standards. Further research would look at a range of issues including the chemical composition of small particles. I strongly support the need for continued scientific research on this and other air pollutants as a high priority. However, as we pursue this research, we must simultaneously take all appropriate steps to protect public health. Because of the magnitude of the risk to the public from fine particles, I have proposed to move ahead with strategies to control these pollutants.

**Access to Raw Data Underlying Ozone  
and Particulate Matter Health Studies**

Many peer-reviewed studies have reported associations between particulate matter and premature death. In the early 1990's, several studies were published showing associations at levels below the current particulate matter standards. Some critics began raising questions about the extent to which the results could be reproduced and the availability of the underlying data. In response, EPA helped to arrange an effort to conduct a reanalysis of several such studies, by an independent group of investigators under the auspices of the Health Effects Institute (HEI), a highly respected research organization jointly funded by EPA and several motor vehicle and engine manufacturers. The original investigators of several studies, including studies conducted at Harvard University, Brigham Young University, and the San Francisco Bay Area Air Quality Management District, provided their raw data sets to the HEI investigation team for reanalysis. HEI's reanalysis produced numerical results from the data sets for all six locations that closely agree with and, in general, confirm those of the original investigators.

These studies have been subjected to an appropriate peer review process when they were published in reputable scientific journals. Given the consistency and coherence of the scientific evidence and the scrutiny the studies have received in peer review and in the extensive scientific review process described above, EPA does not believe that review of the raw data underlying these studies is necessary. Nevertheless, in the interest of facilitating broad public understanding in the rulemaking process, on January 31, 1997, I instructed my staff to write to the principal investigators of the studies in question and urge them to make the data underlying their studies available to interested parties.

As described to us in a recent letter, Harvard University which responded on behalf of the investigators has asked the HEI to establish a process for reviewing the data in the Six Cities Study. While EPA believes that, as a general principle, data underlying these and other studies should be made available, the Agency respects the fact that revealing underlying data can raise significant proprietary, legal and ethical issues concerning confidentiality. Many of these studies use highly personal information, including medical data, which were obtained through promises of confidentiality. Data-sharing arrangements must, therefore, appropriately accommodate interests both in making data accessible to interested scientists and in protecting the confidentiality and proprietary nature of the information contained within them. It appears that the approach being pursued by Harvard with HEI appropriately accommodates these interests. Similarly, the American Cancer Society, which maintains the extensive data underlying the largest of these epidemiological studies, also has an appropriate protocol for public access by qualified researchers.

**Finding Common-Sense, Cost-Effective Strategies  
for Implementing a Revised Ozone or PM Standard**

If we ultimately determine that protection of public health requires the revision of one or both of these standards, new strategies and deadlines must be devised for attaining the revised standards. Under the Clean Air Act, states are primarily responsible for developing and implementing control measures to meet a new or revised national ambient air quality standards. We are determined to help states develop the most cost-effective, innovative strategies for implementation of any new or revised standards, and to ensure a smooth transition from current efforts.

To meet this goal, we have used the Federal Advisory Committee Act (FACA) to establish a Subcommittee for Ozone, Particulate Matter and Regional Haze Implementation Programs. It is composed of almost sixty members of state and local agencies, industry, small business, environmental groups, other federal agencies and other groups and includes five working groups comprised of another 100 or so members of these same kinds of organizations.

The Subcommittee and the various workgroups have been meeting regularly for well over a year to hammer out innovative strategies for EPA and the states to consider in implementing any revised standards. Members from industry, state governments and others are putting forward position papers advocating innovative ways to meet air quality standards. It is our belief that results from this Subcommittee process will lead to innovative approaches for implementing any new standards. The Subcommittee will continue to meet over the next year to help develop cost-effective, common-sense implementation programs.

The issues being addressed by the Subcommittee include:

- What will be the new deadlines for meeting any new standards? [If EPA tightens a standard, it has the authority to establish deadlines of up to ten years -- with the possibility of two additional one-year extensions -- beyond the date an area is designated "nonattainment."]
- What will be the size of the area considered "nonattainment?" [If it revises an air quality standard, EPA has the ability to change the size of the affected nonattainment areas and focus control efforts on those areas that

are causing the pollution problems, not just the downwind areas that are monitoring unhealthy air.]

- How do we address the problem of the pollutants that form ozone and/or fine particles being transported hundreds of miles and contributing to nonattainment problems in downwind areas?
- What kinds of control strategies are appropriate for various nonattainment areas? Can we use the experience of the past several years to help states target those control strategies that are the most cost-effective?
- How can we promote innovative, market-based air pollution control strategies?

The implementation of the revised standards is likely to focus on sources like cars, trucks, buses, power plants and cleaner fuels. In some areas, as with the current standards, our analysis shows that reaching the standards will present substantial challenges. All of the air pollution control programs we and the states are pursuing to meet the current ozone and particulate matter standards, as well as certain programs to implement other sections of the Clean Air Act, will help meet any revised standards. For example, the sulfur dioxide reductions achieved by the acid rain program will help greatly reduce levels of fine particles, particularly in the eastern United States. Cleaner technology in power plants would also greatly reduce the nitrogen oxides that help form ozone across the eastern United States.

### **Response to Small Business Concerns**

In announcing the proposed ozone and particulate matter standards last November, I initiated steps to obtain even broader views of stakeholders on

implementation strategies. We expanded the membership of the Federal Advisory Subcommittee to include more representation from small business and local governments.

We are also following Small Business Regulatory Enforcement Fairness Act (SBREFA) procedures to conduct panels for collecting advice and recommendations on how states could lessen the impacts on small business and other small entities as the states develop their implementation plans. While SBREFA does not apply to states or non-binding EPA guidance to states, we believe that following SBREFA panel procedures and the related FACA activities, will prove very useful in helping us develop guidance and other materials to help and encourage the states to minimize small-business impacts. We are currently considering recommending to the states a number of mitigating measures, such as small-business exemptions, longer compliance schedules, and flexible approaches such as emissions trading. We expect to get more good ideas from small-business representatives as the panel process and FACA meetings proceed. In short, we are taking seriously small business concerns as we look toward implementation of any new or revised standards.

I intend to announce our proposals on implementation of the proposed new standards in phases that correspond to the Federal Advisory Committee Act Subcommittee's schedule for deliberating on various aspects of the program. I have previously stated my intention to propose the first phase of that program at the same time that I announce our final decision on revisions to the ozone and particulate matter standards.

## **Conclusions**



Messrs. Chairmen, the issues we are discussing today are critical to the state of the Nation's public health and environment. It is imperative that the American public understand these important issues. I am hopeful that this and other hearings and public forums will help focus the national debate on the real health and environmental policy implications of these national air quality standards.

In the Clean Air Act, the Congress has given me the responsibility to review every five years the most recent science to determine whether revisions to national air quality standards are warranted. In doing so, the law tells me to protect the public health with an adequate margin of safety.

We are constantly reviewing the science associated with these standards, but we do not often propose revisions to them. I have done so in the case of ozone and particulate matter because of significant new scientific evidence. For the past three-and-a-half years we have targeted our resources to conduct a thorough, intensive review of this scientific evidence. The scope and depth of this review process has been based on virtually unprecedented external peer review activities.

Given the at risk populations affected by these pollutants -- children, asthmatics, the elderly -- as well as possible effects on outdoor workers and other healthy adults, I determined that it was appropriate to propose standards that tended to fall toward the lower end of the range of protection supported by our independent science advisors and recommended by experts in my technical offices. Based on the record before the Agency at the time of proposal, including the advice and recommendations of the CASAC panels, it was my view -- subject to further consideration based on public

comments -- that the proposed standards were requisite to protect public health, including sensitive populations, with an adequate margin of safety.

At the same time, I recognize that the proposed standards involve issues of great complexity and we are currently reviewing a broad range of comments from affected and interested parties. As I have described, we have gone to unprecedented lengths to provide the public with opportunities to express their views on the proposed standards. We also expressly requested comments on options (including alternative levels and forms of the standards) that are both more protective and less protective than the levels we proposed. We intend to give serious consideration to these comments.

Messrs. Chairmen, this concludes my written statement. I will be happy to answer any questions that you might have.